K120681

MAY 15 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name: Kira Gordon
Siemens Healthcare Diagnostics Inc.
511 Benedict Ave,
Tarrytown, NY 10591

Date of Preparation: May 10, 2012

Name of Product: ADVIA® Chemistry Glucose Hexokinase_3 (GLUH_3) reagent

FDA Classification Name: Glucose test system.

Predicate Device:

The following table describes the predicate devices, device classification, regulation and product code associated with this pre-market notification:

New Product	Predicate Device	510(k) number	Device Class	Regulation	Product Code
ADVIA® Chemistry GLUH_3 Reagent (additional plasma type)	ADVIA® Chemistry GLUH_3 Reagent	k101854	Class II	862.1345	CFR

Device Description:

The ADVIA Chemistry Glucose Hexokinase_3 (GLUH_3) method uses a two-component reagent. Sample is added to Reagent 1, which contains the buffer, ATP, and NAD. Absorbance readings of the sample in Reagent 1 are taken and are used to correct for interfering substances in the sample. Reagent 2 is added, which initiates the conversion of glucose and the development of absorbance at 340/410 nm. The difference between the absorbance in Reagent 1 and Reagent 2 is proportional to the glucose concentration.

Intended Use:

For *in vitro* diagnostic use in the quantitative determination of glucose in human serum, plasma, urine and CSF on the ADVIA Chemistry systems. Such measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and insulin overdose.

Comparison to Predicate Device:

A comparison of the important features of the devices are provided in the following table:

Item	New Device	Predicate Device
Analyte	Glucose	Same
Intended Use	For *in vitro* diagnostic use in the quantitative determination of glucose in human serum, plasma, urine and CSF on the ADVIA Chemistry systems. Such measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and insulin overdose	Same
Sample type	human serum, plasma, urine and CSF	Same
Plasma type	Li-Heparin, K-EDTA and Na-Fluoride/K-Oxalate	Li-Heparin, K-EDTA
Instrument to be used	ADVIA Chemistry	Same
Method Principle	based on the method by Slein using hexokinase and glucose-6-phosphate dehydrogenase enzymes.	Same
Calibrators	Siemens Healthcare Diagnostics Chemistry Calibrator REF 09784096	Same
Assay range	4 -700 mg/dL	Same
Accuracy / Correlation	Serum: Y = 1.001x + 0.3; N=99 r=1.000 Plasma (Li-Heparin): Y = 1.001x + 0.2, N=88; r=1.000 Plasma (K-EDTA) Y = 1.002x – 0.0, N=87; r=1.000 Plasma (Na Fluoride/Potassium Oxalate) Y = 1.011x + 0.8, N=82; r=0.999 CSF: Y = 1.005x – 0.1, N=113; r=1.000 Urine: Y = 0.989x – 0.3, N=51; r=1.000	Serum: Same Plasma (Li-Heparin): same Plasma (K-EDTA) Same Plasma (Na Fluoride/Potassium Oxalate) none CSF: Same Urine: Same

Comments on Substantial Equivalence:

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable for this modification.

b. Linearity/assay reportable range:

Not applicable for this modification.

c. Traceability (controls, calibrators, or method):

Not applicable for this modification.

d. Detection limit (functional sensitivity):

Not applicable for this modification.

e. Analytical specificity:

Not applicable for this modification.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable for this modification.

b. Matrix comparison:

56 matched serum and plasma (Sodium Fluoride/Potassium Oxalate) samples were evaluated. Some of these samples were spiked and/or diluted. There were a total of 82 data-points included in calculations. Matrix Comparison between serum and Na Fl plasma tubes using the ADVIA 1650 Chemistry GLUH_3 assay gave the following correlation statistics using the linear regression calculations:

x – serum, y –Sodium Fluoride/Potassium Oxalate plasma

Regression Equation	$S_{y.x}$	r	N	Sample Range
y = 1.011 * x + 0.8 Slope 95% CI: 1.003 to 1.019 Intercept 95% CI: -1.18 to 2.73	6.13	0.999	82	5-691

3. Clinical studies:

a. Clinical sensitivity:

Not applicable for this submission.

b. Clinical specificity:

Not applicable for this submission.

4. Clinical cut-off:

Not applicable for this submission.

5. Expected values/Reference range:

Not applicable for this modification.

Conclusion:

Comparative testing of the ADVIA 1650 Chemistry Glucose Hexokinase_3 reagent using Sodium Fluoride/Potassium Oxalate plasma type demonstrates substantially equivalent performance to the GLUH_3 reagent using serum as a plasma type cleared under k101854.

Kira Gordon
Regulatory Affairs & Compliance
May 10, 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Healthcare Diagnostics Inc.
c/o Kira Gordon
511 Benedict Ave
Tarrytown, N.Y. 10509

MAY 15 2012

Re: k120681
Trade Name: Advia® Chemistry GLUH_3 Reagent
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: CFR
Dated: March 2, 2012
Received: March 6, 2012

Dear Ms Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known):

Device Name:

ADVIA® Chemistry GLUH_3 Reagent

Indication For Use:

For *in vitro* diagnostic use in the quantitative determination of glucose in human serum, plasma, urine and CSF on the ADVIA Chemistry systems. Such measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and insulin overdose.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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